NISSO AMERICA INC.
379 Thornall Street, 5th Floor
Edison, NJ 08837
Phone: (212) 490-0350 Fax: (212) 972-9361

May 1, 2020

OPP Docket
U.S. Environmental Protection Agency
Docket Center (EPA/DC) (28221T)
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

SUBJECT: Comments to the Proposed Interim Decision for Acetamiprid; Case Number 7617; EPA-HQ-OPP-2012-0329

Dear Sir/Madam:

This submission is being made on behalf of Nippon Soda Co., Ltd. [EPA company number 8033].

Nippon Soda Co., Ltd. c/o Nisso America Inc. (Nisso) is hereby providing comments to the US EPA's Proposed Interim Registration Review Decision (PID) for acetamiprid dated January 22, 2020.

The comments below are referenced to pages and sections within the PID document.

Page 16; Freshwater and Estuarine/Marine Invertebrates

PID: "The 96-hour LC50 for freshwater invertebrates is 3.31 ug a.i./L."

Nisso: The endpoint for acute toxicity to freshwater invertebrates of 3.31 µg/L was applied to the risk aquatic risk assessment in the PID. However, in the Preliminary Risk Assessment (PRA) for acetamprid, the most sensitive acute endpoint was a LC_{50} value of 0.0209 mg a.i./L from the study report, Putt, A. (2003) Acetamiprid Technical--Acute Toxicity to Midge (*Chironomus riparius*) Under Static Conditions, which concluded the LC_{50} value of 0.024 mg a.i./L (MRID 45916201). Therefore, 0.0209 mg a.i./L concluded in the PRA should be used for the acute risk assessment.

Page 16; Freshwater and Estuarine/Marine Invertebrates

PID: "The freshwater invertebrate chronic toxicity endpoint (NOAEC = 0.36 ug a.i./L) is based on adult emergence and on the average number of days to emergence."

Nisso: The PID determined the freshwater invertebrate chronic toxicity endpoint was NOAEC = 0.36 µg a.i./L. This NOAEC value was derived from the results of a public domain report (Raby et., al. (2018)). In this public domain report, almost all endpoints with acetamiprid showed

"poor" or "no" concentration-response relationship except for the % complete emergence and % survival at 14-days. The concentrations of the test solutions were analysed by LC-MS/MS; however, the analytical method validation such as recovery rates, matrix effect, stability linearity, etc. was not conducted and the details of the methods were not given. Therefore, it is possible the measured concentrations were underestimated due to measurement error. Hence, neither the observation results nor the measured concentrations are considered reliable.

Conversely, Nisso submitted a chronic toxicity study with *C. riparius* (McElligott, A. (1999) Acetamiprid: Toxicity to the Sediment Dwelling Chironomid Larvae (*Chironomus riparius*) - 28 Days) that was conducted according to GLP regulations (MRID 50643901). This study resulted in a good concentration-response relationship and the measured concentrations were analysed by a validated analytical method.

The Nisso GLP study has not been reviewed completely by EPA at this time. Therefore we respectfully suggest the Agency continue to review this GLP study and apply the resulting NOEC of 5 µg/L to the aquatic risk assessment for acetamiprid.

Page 14: Potential Pollinator Data Requirements

On page 14 of the PID, the Agency states, "...the EPA is currently determining whether additional pollinator data are needed for acetamiprid" and "The pollinator studies that could be required are listed on Table 1." Nisso respectfully reminds the Agency that we previously submitted numerous pollinator studies (both *Apis* and *non-Apis*) including "Tier 1" acute and chronic toxicity studies with adults and larvae as well as several "Tier 2" semi-field studies. We believe the existing data on-hand at the Agency are sufficient for regulatory purposes and no further data are needed to conduct risk assessments.

Page 28; Proposed Labeling Changes

A sentence in the Agency's proposed pollinator advisory language reads: "This product is moderately toxic to bees and other pollinating insects exposed to direct treatment, or to residues in/on blooming crops or weeds." Nisso is proposing to delete text in the sentence related to residues in/on blooming crops or weeds since the Agency states on page 14 of the acetamiprid PID:

> "Measured residue data suggest that the actual residues of acetamiprid on treated plants may be up to 99% lower than the estimated environmental concentrations (EECs) used to generate RQs. Moreover, though there are risks of concern to individual honey bees, which serve as surrogate for non-*Apis* bees, colony-level studies show that these risks are not likely to translate into long-term adverse effects on the colony. These studies indicate that adverse effects of acetamiprid are likely transitory and so will probably not pose long-term risks to colony health"

Our suggestion acknowledges the empirical data available on acetamiprid residues as it relates to honey bee exposure. Hence, we propose the following text: "This product is moderately toxic to bees and other pollinating insects exposed to direct treatment."

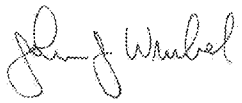
Other Labeling Suggestions (Not Referenced in the PID)

Nisso's acetamiprid product labels for ASSAIL 70 WP (EPA Reg. No.8033-23) and ASSAIL 30 SG (EPA Reg. No. 8033-35) currently contain the following statement: "Do not cultivate or plant crops within 10 feet of aquatic areas as to allow growth of a vegetative filter strip." For parity

with other product labels requiring vegetative filter strips around aquatic areas, we are proposing that the aforementioned filter strip statement be followed by: "Western irrigated agriculture is exempt from this requirement. Western irrigated agriculture is defined as irrigated farmland in the following states: WA, OR, CA, ID, NV, UT, AZ, MT, WY, CO, NM, and TX (west of I-35)."

Thank you for the opportunity to provide comments to the PID for acetamiprid. If you have any questions concerning this information, please feel to contact me at 212-490-0351.

Respectfully submitted,



John J. Wrubel
Vice President